Innovative Use of High-Fidelity Lung Simulators to Test a Ventilator Splitter Device

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The coronavirus disease 2019 (COVID-19) pandemic has rapidly exposed health care system inadequacies. Hospital ventilator shortages in Italy compelled US physicians to consider creative solutions, such as using Y-pieces or T-pieces, to preclude the need to make decisions of life or death based on medical equipment availability. We add to current knowledge and testing capacity for ventilator splitters by reporting the ability to examine the functionality of ventilator splitters by using 2 high-fidelity lung simulators. Data obtained by the high-fidelity lung simulators included: tidal volume, respiratory rate, minute ventilation, peak inspiratory pressure, peak plateau pressure, and positive end-expiratory pressure. (A&A Practice. 2020;14:e01253.)

GLOSSARY

3D = 3-dimensional; **BPM** = breaths per minute; **COVID-19** = coronavirus disease 2019; **EQUATOR** = Enhancing the Quality of and Transparency of Health Research; **FDA** = Food and Drug Administration; **IRB** = institutional review board; **LLEAP** = Laerdal Learning Application; **MV** = minute ventilation; **PEEP** = positive end-expiratory pressure; **PIP** = peak inspiratory pressure; **PPLAT** = peak plateau pressure

The coronavirus disease 2019 (COVID-19) pandemic exposed many health care system inadequacies. Hospital ventilator shortages in Italy compelled US physicians to develop innovations to mechanically ventilate multiple patients with a single machine.[1] One common remedy utilizes Y- or T-pieces to split ventilator tubing enabling simultaneous ventilation of 2 patients with 1 ventilator. However, this poses several patient safety issues including:

- volume delivery to the most compliant lung segments;
- inability to control positive end-expiratory pressure (PEEP);
- inaccurate respiratory parameter measurements;
- alarm malfunction and fatigue;
- complex data interpretation and clinical reasoning for medical decision-making; and
- additional monitoring necessary for medical management.[2]

Innovations and freeware using 3-dimensional (3D)-printed ventilator parts allow for an optional inspiratory limb flow limiter to account for differential lung compliance.[3] Clarke[4] published a similar 3D-printed design and tested the system with 2 reservoir bags as simulated lungs. The idea of splitting 1 ventilator with 22-mm connectors originated in the emergency medicine literature.[5] This setup was tested in the clinical setting during the 2017 Las Vegas mass shooting due to the high number of patients who required mechanical ventilation and the shortage of hospital ventilators.[6] We add to current knowledge and testing capacity for ventilator splitters by reporting the ability to examine the functionality of ventilator splitters by using 2 high-fidelity lung simulators (Figure 1).

The Indiana University Institutional Review Board (IRB) approved the request for exemption from IRB review submitted by the authors #1801644617. This article adheres to the applicable Enhancing the Quality of and Transparency of Health Research (EQUATOR) guideline.

INNOVATION REPORT

To address the previously described patient safety issues associated with the ventilation of multiple patients using 1 ventilator,[2] a team at Eli Lilly (Eli Lilly & Co, Indianapolis, IN) developed a ventilator splitter device (patent, Food and Drug Administration [FDA] approval, and publication pending), and partnered with our academic health care team to substantiate proof of concept, inform iterative design, conduct feasibility studies, and perform pilot testing. Using 2 high-fidelity lung simulators (IngMar ASL 5000 Lung Solution with Breathing Simulator and Lung Adaptor; IngMar Medical, Pittsburgh, PA)[7] with 2 manifold-driven, high-fidelity, adult manikins (Laerdal SimMan 3G advanced patient simulator, Laerdal Medical, Stavanger, Norway) ventilated by 1 ventilator (General Electric Datex Ohmeda Aestiva 3000 Anesthesia Machine with 7900 SmartVent; GE Healthcare, Chicago, IL; and Servo-i Ventilator; Getinge, Göteborg, Västra Götaland County, Sweden), we were able to provide crucial testing with a high level of accuracy and robust data analysis (Figure 2).

All machines performed with only a few crashes attributed to overuse because no causes were identified after searching software logs. The machines ran for 12 days at an

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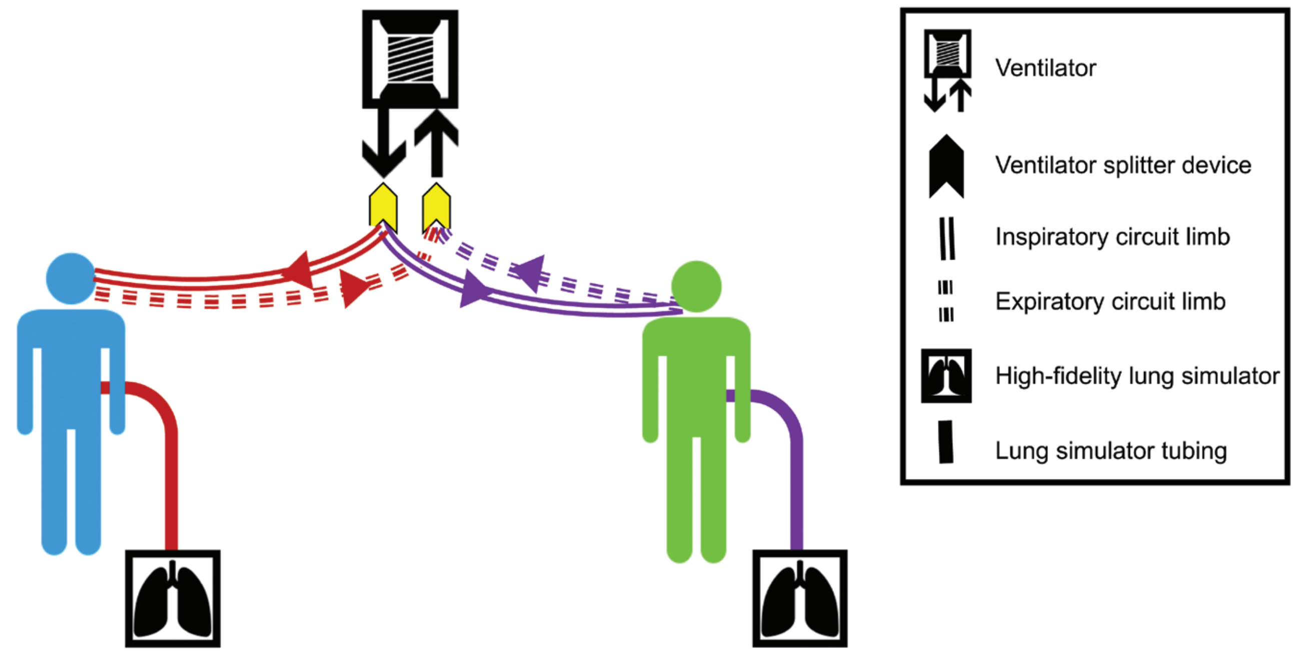

Figure 1. This diagram illustrates the arrangement of equipment for testing the ventilator splitter devices. Each high-fidelity lung simulator is attached to one high-fidelity manikin; thus, independent ventilatory parameters can be set to mimic 2 different patients. Each high-fidelity manikin is intubated with an oral endotracheal tube connected to a double-limb airway circuit. Two ventilator splitters are inserted in-line at the ventilator inspiratory and expiratory connections, which permits connection of the 4 airway circuit limbs (ie, 2 inspiratory and 2 expiratory limbs).

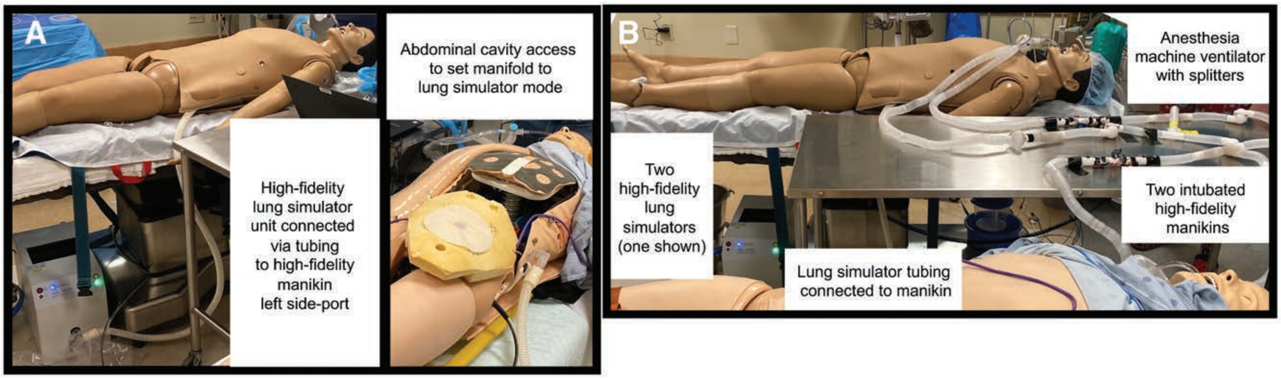

Figure 2. Connection of lung simulators to manikins, access to the manifold switch, and high-fidelity simulators connected to a single ventilator during testing scenarios. A, The manikin abdominal/chest cavity is accessed to install the manifold switch and electronic connections required to pair the manikin with the lung simulator. The manifold is set to lung simulator mode, and the lung-manikin circuit tubing is connected to the manikin via the left-side port. B, This set up permitted testing of the ventilator splitter device for performance, clinical applicability, troubleshooting, and documentation of feasibility to simultaneously yet independently ventilate 2 patients using a single ventilator. Findings informed iterative design of the device. The device was also tested for durability as the machines ran for an average of 7.91 h/d for 12 d.

average of 7.91 h/d. To our knowledge, neither the IngMar ASL 5000 nor the Laerdal SimMan 3G manikin have run for this length outside of manufacturer testing. This extensive duration of testing was vital to ascertain the ventilator splitter durability, which would be required for long-term ventilation of patients with COVID-19.

Data obtained by the high-fidelity lung simulators included: tidal volume, respiratory rate, minute ventilation, peak inspiratory pressure, peak plateau pressure, and PEEP (Figure 3). Our team of anesthesiologists and intensivists provided feedback through the lens of expertise in patient care, mechanical ventilation management, and clinical applications of the ventilator splitter. The testing guided iterative improvements in the ventilator splitter and confirmed the absence of any performance issues. Thus, the high-fidelity lung simulators facilitated demonstration of the durability, efficacy, and safety of the ventilator splitter device.

DISCUSSION

We report the first use of 2 high-fidelity lung simulators with 2 high-fidelity manikins and a ventilator to perform testing of a ventilator splitter device. This project was made possible, in part, by high-fidelity lung simulators with National Institute of Standards and Technology calibrated measurements. The high-fidelity lung simulators and high-fidelity manikins have clearly demonstrated value to our institution, community, and the patients for which we care in preparing for this pandemic.

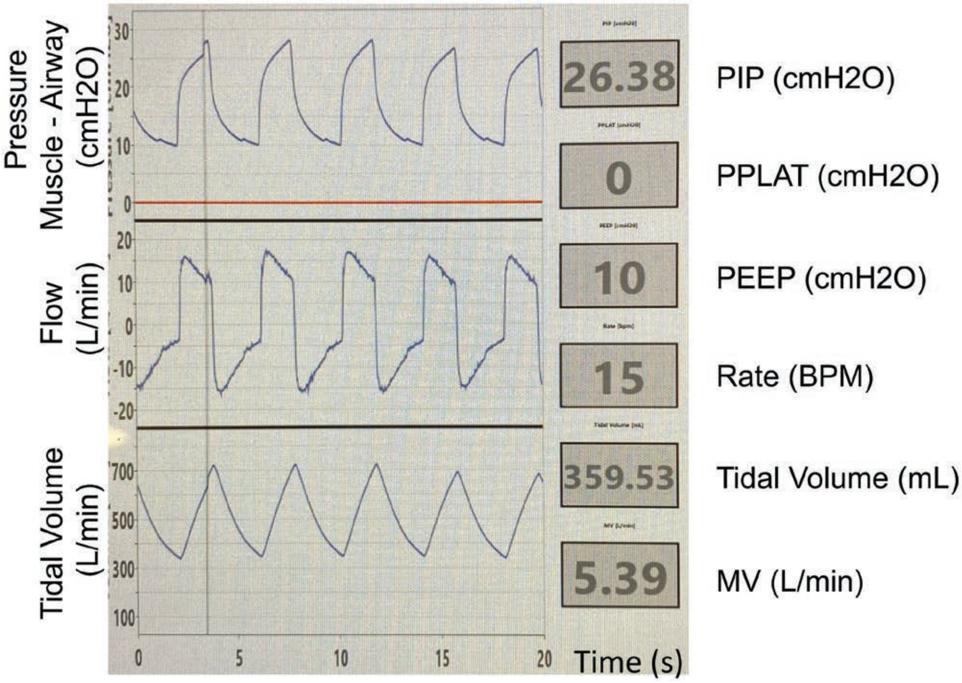

Figure 3. The high-fidelity lung simulator is electronically controlled using LLEAP software (Laerdal Medical, Wappingers Falls, NY). Output data formats are graphical and numerical ventilatory parameters. These waveforms and values mirror the parameters shown to clinicians on the ventilator monitor screen. Clinicians use these parameters to make decisions to guide medical management, treatment, therapeutic interventions, and diagnostic tests. BPM indicates breaths per minute; LLEAP, Laerdal Learning Application; MV, minute ventilation; PEEP, positive end-expiratory pressure; PIP, peak inspiratory pressure; PPLAT, peak plateau pressure.

We share this experience with the medical community so that this technology can be used across professions to rapidly facilitate translational testing of medical ventilator solutions. This project substantiates the capacity of industry–academic–health care partnerships to investigate innovative solutions through rapid-cycle product development and testing, and holds promise for future interdisciplinary and interprofessional collaborations.

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DISCLOSURES

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Contribution: This author was instrumental in the feasibility studies and novel pilot studies using the high-fidelity lung simulator; helped analyze and interpret the data for the work, compose and edit the article, and approve the final article for publication; and agrees to be accountable for all aspects of the work in ensuring that questions related to any part of the work are appropriately investigated and resolved.
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